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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No. 10/790,027 Confirmation No. Unassigned  
Applicant John A. GIORDANO et al.  
Filed 2 March 2004  
TC/Art Unit Unassigned  
Examiner Unassigned  
  
Docket No. 48508-00014  
Customer No. 23767

PATENT OFFICE FEE TRANSMITTAL LETTER

Commissioner for Patents  
Alexandria, VA 22313

Sir:


The following fees are enclosed in connection with the filing of the attached papers:

**Petition Filing Fee.....\$130.00**

It is not believed that any further fees are due in connection with the filing of the attached papers. However, the Commissioner is authorized to charge any underpayment or credit any overpayment of fees to the undersigned's deposit account no. 50-1067.

Respectfully submitted,

22 March 2004

  
\_\_\_\_\_  
Guido J. Galvez  
Reg. No. 52,933

Preston Gates Ellis & Rouvelas Meeds LLP  
1735 New York Avenue NW, Suite 500  
Washington, DC 20006  
Telephone : (202) 628-1700  
Facsimile : (202) 331-1024



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Applicant	John A. GIORDANO et al.		
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STATEMENT IN SUPPORT OF PETITION TO MAKE SPECIAL  
UNDER 37 C.F.R. § 1.102 AND M.P.E.P. § 708.02(II)

Commissioner for Patents  
Alexandria, VA 22313

Sir:

Pursuant to M.P.E.P. § 708.02 (II), and in addition to the Petition To Make Special filed concurrently herewith, the undersigned hereby states:

1. That there is an infringing product actually on the market. *See* copy of Product Package and Label, attached as Exhibit A.
2. That a rigid comparison of the alleged infringing product with the claims of the present application has been made.
3. That, in my opinion, some of the claims are unquestionably infringed.
4. That I have caused to be made a careful and thorough search of the prior art.
5. That the results of that prior art search are provided in the concurrently submitted Information Disclosure Statement and associated PTO/SB/08A, or were provided in the previously submitted Information Disclosure Statement and associated PTO/SB/08A.

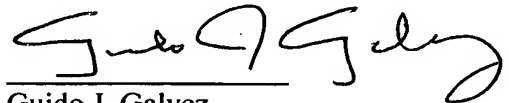
All statements made herein of their own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or

Serial No. 10/790,027

Atty. Docket No. 48508-00014

imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent resulting therefrom.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Guido J. Galvez", written over a horizontal line.

Guido J. Galvez  
Reg. No. 52,933

22 March 2004

Preston Gates Ellis & Rouvelas Meeds LLP  
1735 New York Ave., N.W.  
Washington, DC 20006  
Telephone: (202) 628-1700  
Facsimile: (202) 331-1024

NDC 64980-120-01

# Rising Natafolic-OB

## PRENATAL

MULTI-VITAMIN  
MULTI-MINERAL  
SUPPLEMENT

**RX ONLY**

Manufactured for:  
RISING PHARMACEUTICALS, INC.  
Paramus, NJ 07652

Manufactured by:  
Contract Pharmaceutical Corp.  
Hauppauge, NY 11788

100 CAPLETS 10 X 10 UNIT DOSE PACK

### Indications and Uses

Natafolic-OB is indicated to provide vitamin and mineral supplementation throughout pregnancy and during the postnatal period for the lactating and non-lactating mother. It is also useful for improving the nutritional status prior to conception.

Natafolic-OB: Contains 1 mg. folic acid, which is very important in the development of the baby's spinal column during a specific period of time. Women are advised to start taking folate supplementation several weeks before conception and to continue taking them through the first 12 weeks of pregnancy, or longer. It is recommended that all women of childbearing years take folic acid supplementation.

### Contraindications

Folic acid (pteroylglutamic acid) is contraindicated in patients with untreated and uncomplicated pernicious anemia, and in those with anaphylactic sensitivity to folic acid. Iron therapy is contraindicated in patients with hemochromatosis and patients with iron storage disease or the potential for iron storage disease due to chronic hemolytic anemia (e.g., inherited anomalies of hemoglobin structure or synthesis and/or red cell enzyme deficiencies, etc.), pyridoxine responsive anemia, or cirrhosis of the liver. Cyanocobalamin is contraindicated in patients with sensitivity to cobalt or to cyanocobalamin (Vitamin B-12).

### Warnings

Pernicious anemia should be ruled out before starting treatment. While folic acid corrects the blood picture of pernicious anemia, it does not ameliorate the attendant neurologic involvement.

Resistance to treatment may be due to depressed hematopoiesis, alcoholism, the presence of anti-metabolic drugs, and to deficiencies of vitamins.

Prolonged use of iron salts may produce iron storage disease.

100 CAPLETS 10 X 10 UNIT DOSE PACK

adverse effects (pteroylglutamic acid) and Vitamin B-12 microbiological blood assays are invalidated by the administration of most antibiotics, methotrexate, and pyrimethamine. Folic acid (pteroylglutamic acid) is not effective reversing the toxic effects of methotrexate. Folic acid (5-formyltetrahydrofolic acid) must be used in that situation. Black tarry stools may be due to either occult GI bleeding or iron therapy or both.

Folic acid may partially correct the hematological damage due to Vitamin B-12 deficiency of pernicious anemia, while the associated neurological damage progresses. In rare instances, allergic sensitization has been reported following both oral and parenteral administration of folic acid.

Supplementation of the diet by milk or other dietary sources of calcium may be advisable.

### Adverse Reactions

Allergic sensitivity reactions and gastrointestinal disturbances may occur.

### Dosage and Administration

Before, during and after pregnancy, one caplet daily, or as directed by a physician.

### How Supplied

Natafolic-OB is available as a light blue caplet, imprinted "RIS 120". Available in Box of Unit-Dose pack of 100 (10 x 10).

### Rx Only

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

Store at 20° - 25°C (68° - 77°F); excursions to 15° - 30°C (59° - 86°F).

**WARNING:** Accidental overdose of iron containing products is a leading cause of fatal poisoning in children under 6. Keep this product out of reach of children. In case of accidental overdose, call a doctor or Poison Control Center immediately.

100 CAPLETS 10 X 10 UNIT DOSE PACK

# Rising Natafolic-OB Prenatal

One caplet daily provides:

	Amount Per Caplet 2700 I.U.
Vitamin A (Beta Carotene)	2700 I.U.
Vitamin C (Ascorbic Acid)	70 mg.
Vitamin D-3 (Cholecalciferol)	400 I.U.
Vitamin E (dl-Alpha Tocopheryl Acetate)	30 I.U.
Vitamin B-1 (Thiamine Mononitrate)	1.6 mg.
Vitamin B-2 (Riboflavin)	1.6 mg.
Niacin (Nicotinamide)	18 mg.
Vitamin B-6 (Pyridoxine HCl)	2.5 mg.
Folic Acid	1 mg.
Vitamin B-12 (Cyanocobalamin)	12 mcg.
Calcium (Calcium Carbonate)	100 mg.
Iron (Ferrous Fumarate)	65 mg.
Magnesium (Magnesium Oxide)	28 mg.
Zinc (Zinc Oxide)	25 mg.
Copper (Cupric Oxide)	2 mg.

Other Ingredients: Acacia, Ascorbyl Palmitate, Croscarmellose Sodium, Dicalcium Phosphate, FD&C Blue #1 Lake, FD&C Yellow #5 Lake, Gelatin, Hydroxypropylmethylcellulose, Magnesium Stearate, Magnesium Silicate, Maltodextrin, Microcrystalline Cellulose, Mineral Oil, Polyethylene Glycol, Polyvinylpyrrolidone, Silica, Sodium Ascorbate, Starch, Stearic Acid, Sucrose, and Titanium Dioxide.

\*Contains FD&C Yellow #5 Lake (Tartrazine) as a color additive.

**WARNING:** Accidental overdose of iron containing products is a leading cause of fatal poisoning in children under 6. Keep this product out of reach of children. In case of accidental overdose, call a doctor or Poison Control Center immediately.

# Rising Natafolic-OB

## PRENATAL

10 X 10 Unit Dose Pack  
100 Caplets

MULTI-VITAMIN  
MULTI-MINERAL  
SUPPLEMENT



NDC 64980-12001-2

LOT # 032975  
EXP 7/05